

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte RAYMOND J. BERGERON, JR. and CHARLES A. SNINSKY

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Appeal No. 1999-1949  
Application No. 08/481,863

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HEARD: October 23, 2001

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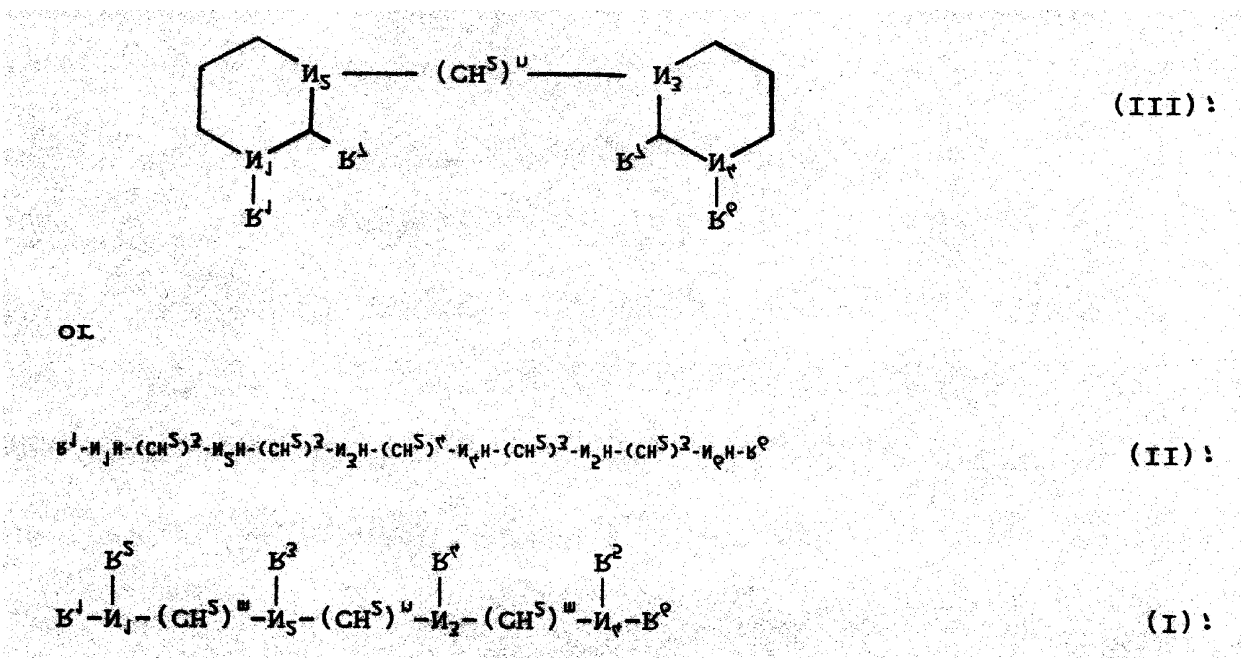
Before WINTERS, ROBINSON, and MILLS, Administrative Patent Judges  
ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claim 19. Claim 9, the only other pending claim, has been indicated allowable by the examiner.

Claim 19 reads as follows:

19. An anti-diarrheal or gastrointestinal anti-spasmodic pharmaceutical composition comprising an antidiarrheal, gastrointestinal anti-secretory, nitric oxide agonist or nitric oxide synthase activating or gastrointestinal antispasmodic effective amount of a compound having the formula:



wherein:

$R_1$  and  $R_6$  may be the same or different and are H, alkyl or aralkyl having from 1 to 12 carbon atoms, provided that, in formula (I),  $R_1$  and  $R_6$  are not H;  
 $R_2$ - $R_5$  may be the same or different and are H,  $R_1$  or  $R_6$  ;  
 $R_7$  is H, alkyl, aryl or aralkyl having from 1 to 12 carbon atoms;  
 $m$  is an integer from 3 to 6, inclusive;  
 $n$  is an integer from 3 to 6, inclusive; or

(IV) a salt thereof with a pharmaceutically acceptable acid; and a pharmaceutically acceptable carrier therefor.

The references relied on by the examiner are listed below:

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Ray

4,591,605

May. 27, 1986

Weinstock et al. (Weinstock) "Synthesis of New Polyamines Derivatives for Cancer Chemotherapeutic Studies," Journal of Pharmaceutical Sciences Vol. 70, pp. 956-959 (1981)

### **Grounds of Rejection**

Claim 19 stands rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies, alternatively, on Weinstock and Ray.

We reverse the rejection under 35 U.S.C. § 103 based on Weinstock and vacate the rejection under 35 U.S.C. § 103 over Ray for the reasons set forth herein.

### **Background**

The presently claimed invention is directed to a pharmaceutical composition indicated to be useful as an anti-diarrheal or gastrointestinal antispasmodic treatment which is comprised of a polyamine compound selected from three structurally defined compounds or the pharmaceutically acceptable acid salts thereof.

### **Discussion**

The rejections under 35 U.S.C. § 103

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In rejecting claim 19 under 35 U.S.C. § 103 as being obvious over Weinstock, the examiner relies on Weinstock as describing "compound (IIIe), that is, tetramethylspermine which is embraced by the instant genus and which was tested for anti-cancer activity against P-388 leukemia cells and gave a T/C (test/control) of 110 at a dose of 100mg/kg." (Answer, page 3). The examiner acknowledges that Weinstock does not explicitly recite a composition which includes compound IIIe, but urges that (Answer, page 4):

the mere testing of said compound for anti-cancer activity implies a composition thereof since the compound must necessarily be in solution for testing, most likely in an aqueous solution which reads on applicant's [sic] composition. Furthermore, it is obvious to add a carrier or solvent to an unpatentable or known compound; combination does not become new and patentable because of [the] presence of solvent or carrier. (Citation omitted.).

The examiner concludes that (id.):

it would have been prima facie obvious to one having ordinary skill in the art at the time the application was filed to prepare a composition of the known compound IIIe, that is, at least dissolve [sic, dissolve] it in water because not only do Weinstock et al use of said compound for anti-cancer testing implies a composition thereof, but also wherein such an expedient is considered to be routine and obvious to the ordinary skilled artisan, absent some unobvious or unexpected results.

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In rebuttal, appellants concede that 1) compound IIIe of Weinstock is embraced by the generic structural formula of claim 19; 2) compound IIIe was subjected to screening in mice with leukemia P-388; and 3) compound IIIe was administered to test animals. (Brief, page 8). However, appellants urge that (Brief, page 9):

the teachings of Weinstock do not, however, even when coupled with the above-discussed concessions by appellants, constitute a prima facie case of obviousness.

Appellants argue that Weinstock “does not disclose a pharmaceutical composition containing an effective amount of a compound IIIe or any other polyamine embraced by the generic formulae of claim 19.” (Id.). The appellants, additionally, argue that Weinstock explicitly states that “[n]one of the polyamines showed good activity against leukemia P-388.” (Id.). Thus, appellants urge that Weinstock could not have suggested an effective amount of compound IIIe for any purpose since they are not disclosed as effective for any purpose.

The examiner responds by urging that “all that is required is a suggestion or motivation to make the modification which exist in Weinstock’s intended pharmaceutical use of the compound and the testing thereof for anti-cancer activity.” (Answer, page 5). However, Weinstock does not describe a therapeutic or pharmaceutical use for the compound in question. While a screening test is run on the compound to test

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effectiveness in the treatment of leukemia P-388, the reference would reasonably appear to state that the polyamines, of which compound IIIe is one, were ineffective. Thus, Weinstock does not serve to establish that compound IIIe was known in the prior art to have any use whatsoever. Therefore, to the extent that the examiner would urge that it would have been obvious to combine excipients with a known compound, apparently based on their intended use as a pharmaceutical, the evidence provided fails to establish that the compound in question was known to have any particular pharmaceutical activity which would have served to suggest its use with excipients.

As to the examiner's speculation or assumption, that in order to have tested compound IIIe in animals it would have been necessary to use compositions, such as aqueous composition, we find nothing in the reference and the examiner has provided no evidence or facts which would reasonably support this proposition. As pointed out by appellants, (Reply Brief, page 15) the compound IIIe could have been administered to the test animal in pure form rather than as a diluted composition. Since a rejection under 35 U.S.C. § 103 can not be based on speculations and assumptions, (See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967); In re Steele, 305 F.2d 859, 862-63, 134 USPQ 292, 295-96 (CCPA 1962) and In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)), the lack of substantive evidence which

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would reasonably support the examiner's position in this regard is further evidence that Weinstock does not provide a sufficient basis to question the patentability of appealed claim 19 under 35 U.S.C. § 103.

Thus, we find that the examiner has failed to provide sufficient evidence to reasonably support a conclusion that the appealed claims would have been obvious within the meaning of 35 U.S.C. § 103 over the teaching of Weinstock. Therefore, we reverse this rejection.

In rejecting claim 19 under 35 U.S.C. § 103 as unpatentable over Ray the examiner urges that "Ray teaches a genus of polyamines having anti-secretory activity which embraces the compounds of the instant claim." (Answer, page 4). The examiner concludes that (id.):

it would have been prima facie obvious to one having ordinary skill in the art at the time the application was filed to choose a species from a prior art genus, motivation being that said species would be expected to possess the same or similar properties as its exemplified counterparts, in this case inhibition of stomach acid secretion . . . .

The examiner subsequently urges that "some of the compounds exemplified by Ray (see 1, 2 and 6) are merely obvious variants of applicant's [sic] compounds which in turn are generically taught by Ray . . . ." (Answer, page 8).

To the extent that we understand the examiner's position, it remains that the examiner's statements and reasoning in support of this rejection fail to adequately address the teachings of Ray as they relate to the claimed subject matter in a manner which would permit meaningful review on our part. Initially, we would note that the examiner's statement that it would be obvious to choose a species from the genus of Ray does not appear relevant to the case at hand since the appealed claim is not drawn to a specie but is drawn to compositions containing generically defined compounds. To the extent that the examiner urges that Ray discloses compounds which are merely obvious variants of applicants' compounds, it remains that the examiner has failed to provide substantive evidence or reasoning which would indicate what modifications of Ray would have been necessary to arrive at the claimed invention, what would have served to lead one of ordinary skill to make those modifications and why such modifications would have been motivated given the state of the art relating to this subject matter. Therefore, we vacate this rejection.

Should further prosecution occur in this application we leave to the examiner to reconsider whether a rejection of pending claim 19 is appropriate based on Ray or any other prior art. In so doing, we would encourage the examiner, should it be determined that such a rejection is appropriate, to make use of the approach provided in MPEP § 706.02(j). See also Graham v. John Deere Co., 383 U.S. 1,17, 148 USPQ



459, 467 (1966)("Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined."). In addition, we would also encourage the examiner to review the claims, directed to compositions containing polyamines of the type required by appealed claim 19, present in U. S. Patents<sup>1</sup> 5,393,757; 5,455,277; 5,681,837; 5,866,613; and 6,235,794 B1, each of which would reasonably appear to be similar to or at least closely related to the subject matter of appealed claim 19. We would note, that in each case, Ray was listed on the front of the patent as being considered during the prosecution of each of these patents. Thus, it is not readily apparent why claims directed to these closely related polyamine containing compositions would be considered patentable in these patents, but not patentable over this same reference in the present application. While the examiner may issue a rejection under these circumstances, if appropriate, a rejection using the rationale set forth above would appear to require the signature of the Group Director. Compare, MPEP § 2307.02 (7th ed., July 1998). We note that the Group Director did not sign any office action in which this rejection appears, including the Examiner's Answer.

### **SUMMARY**

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<sup>1</sup> Copies attached.

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To summarize, the rejection of claim 19 under 35 U.S.C. § 103 as unpatentable over Weinstock is reversed. The rejection of claim 19 under 35 U.S.C. § 103 as unpatentable over Ray is vacated.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)

**VACATED and REVERSED**

Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Douglas W. Robinson	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Demetra J. Mills	)	
Administrative Patent Judge	)	

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